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MARYLAND HEALTH
CARE COMMISSION

2401 West Belvedere Avenue
Baltimore, MD 21215-5271
410-601-9670
410-601-8801 fax

Joel I. Suldan
Vice President
General Counsel

August 30, 2007

**VIA E-MAIL AND
FIRST CLASS MAIL**

David A. Neumann, Ph.D.
Center for Hospital Services
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Proposed COMAR 10.24.05 – Research Waiver Applications: Atlantic C-Port Study of Nonprimary PCI, as published in the Maryland Register on August 3, 2007.

Dear Dr. Neumann:

This letter sets forth the comments of LifeBridge Health, Inc. ("LifeBridge") on the above-referenced proposed regulations (the "Proposed Regulations"). LifeBridge is the largest and most comprehensive provider of health-related services in Northwest Baltimore, and includes Sinai Hospital, Northwest Hospital, and Levindale Hospital. Sinai Hospital offers both open heart surgery and angioplasty services.

Background

On May 10, 2007, the staff of the Maryland Health Care Commission published on the Commission's website draft proposed regulations for Research Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Non-Primary Percutaneous Coronary Interventions Performed in Maryland Hospitals without On-Site Cardiac Surgery (the "Draft Proposed Regulations"). On May 24, 2007, LifeBridge submitted comments to the Draft Proposed Regulations.

Based on the comments received on the Draft Proposed Regulations, the Commission approved certain changes to the Draft Proposed Regulations, and the revised Proposed Regulations were published in the Maryland Register on August 3, 2007.

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Incorporation by Reference of Previous Comments:

LifeBridge hereby incorporates all of its comments (except for the item described in the following paragraph) as set forth in the letter dated May 24, 2007, from Warren A. Green to David A. Neumann, Ph.D.

One of comments made by LifeBridge in the May 24, 2007 letter was that 10.24.05.04.A(3) should require the Commission to consider certain enumerated factors in determining whether to grant a waiver application. LifeBridge acknowledges that the Proposed Regulations incorporate this change, and LifeBridge respectfully withdraws its comments suggesting that the consideration of the enumerated factors be mandatory.

Additional Comments

In addition to the comments previously submitted in the letters identified above, LifeBridge respectfully submits the following additional comments:

10.24.05.04.A(2)(c) and 10.24.05.06.A(4):

The Draft Proposed Regulations required that an applicant perform 200 PCIs per year. Based on comments received by the C-PORT investigator and certain other parties, the Commission revised this requirement to require that an applicant need only perform 100 PCI procedures in the first year of its waiver.

As set forth in LifeBridge's previous comments on the Draft Proposed Regulations, it is well established that, with respect to PCI, volume is directly related to quality. For that reason, the American College of Cardiology and American Heart Association currently recommend that PCI only be performed in hospitals that perform at least 400 PCI procedures annually.

As LifeBridge has previously noted, we believe that the risks to subjects participating in this study are not outweighed by the benefits of the study. However, by lowering the first year standard to 100 PCI procedures, the Proposed Regulations will put people at even greater risk. Accordingly, LifeBridge urges the Commission, at the least, to reinstate 200 PCI procedures as the absolute minimum annual volume that a waiver hospital must meet to participate in the study.

Thank you for considering our comments on the Proposed Regulations.

Sincerely yours,



Joel I. Suldán
Vice President and General Counsel